NOV 2 2 2013

Section 3 510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: K132588

1. Date of Submission: Jul 20, 2013

2. Sponsor Identification

Top-Rank Health Care Co., Ltd
Chencun Village, Dongguan Street, Shangyu, Zhejiang, 312352, China

Establishment Registration Number: 3006626283

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Position: Management Representative
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3. Submission Correspondent

Ms. Diana Hong& Mr. Lee Fu
Mid-Link Consulting Co., Ltd
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4. Proposed Device Identification

Proposed Device Name: Adhesive Electrodes
Proposed Device Common Name: Electrode

Regulatory Information:
Classification Name: Cutaneous Electrode;
Classification: II;
Product Code: GXY;
Regulation Number: 21 CFR 882.1320;
Review Panel: Neurology;

Intended Use Statement:
Adhesive electrodes are intended for use as the disposable, conductive adhesive interface between the patient's skin and the Electrical Stimulator. Top-Rank Adhesive Electrodes are intended to be used with marketed Electrical Stimulators, i.e. TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation). It is for OTC use.

5. Predicate Device Identification

510(k) Number: K070612
Product Name: Top-Rank Adhesive Electrodes
Manufacturer: Top-Rank Health Care Co., Ltd.

6. Device Description

Adhesive electrodes are intended for use as the disposable, conductive adhesive interface between the patient's skin and the Electrical Stimulator. Top-Rank Adhesive Electrodes are intended to be used with marketed Electrical Stimulators, i.e. TENS (Transcuaneous Electrical Nerver Stimulation) and EMS (Electrical Muscular Stimulation). It is for OTC use.

The proposed device, Adhesive Electrode, is intended to be used with U.S. legally marketed Electrical Stimulator, i.e. TENS and EMS, as a conductive adhesive interface between the patient's skin and such stimulators. It is for single patient use only.

The proposed device mainly consists of substrate and wire. The substrate is available in rectangular shape and round shape.

7. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:

ANSI/AAMI HF18:2001 Electrosurgical devices

8. Substantially Equivalent (SE) Conclusion

The following table compares the DEVICE to the predicate device with respect to intended use, design feature and performance, etc.

Table 3-1 Comparison of Technology Characteristics

ITEM	PROPOSED DEVICE Adhesive Electrodes	PREDICATE DEVICE Top-Rank Adhesive Electrodes, K070612
Device Name	Adhesive Electrodes	Top-Rank Adhesive Electrodes
Regulation Number	882.1320	882.1320
Product Code	GXY	GXY
Classification Name	Cutaneous Electrode	Cutaneous Electrode
Device Class	CLASS II	CLASS II
Intended Use	Adhesive electrodes are intended for use as the disposable, conductive adhesive interface between the patient's skin and the Electrical Stimulator. Top-Rank Adhesive Electrodes are intended to be used with marketed Electrical Stimulators, i.e. TENS (Transcuaneous Electrical Nerver Stimulation) and EMS (Electrical Muscular Stimulation). It is for OTC use.	Top-Rank Adhesive Electrodes are intended for use as the disposable, conductive adhesive interface between the patient's skin and the Electrical Stimulator. Top-Rank Adhesive Electrodes are intended to be used with marketed Electrical Stimulators, i.e. TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation).
Design Feature	Substrate / Wire / Hydro-Gel Scrim / Conductive Fiber Carbon Conductive Film / Liner	Same
Labeling	Conforms to 21 CFR 801	Same
OTC or Prescription	For OTC use	For prescription use
Biocompatibility	Complies with ISO 10993	Complies with ISO 10993
Performance	Complies with ANSI/AAMI HF18:2001	Complies with ANSI/AAMI HF18:2001 E

The proposed device, Adhesive Electrodes, is determined to be Substantially Equivalent (SE) to the predicate device, Top-Rank Adhesive Electrodes (K070612), in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

November 22, 2013

Top Rank Health Care Equipment Co., Ltd
C/O Ms. Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai
China 200120

Re: K132588
Trade Name: Adhesive Electrode
Regulation Number: 21 CFR 882.1320
Regulation Name: Cutaneous electrode
Regulatory Class: Class II
Product Code: GXY
Dated: November 8, 2013
Received: November 12, 2013

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health
Enclosure

Indications for Use

510(k) Number (if known): K132588

Device Name: Adhesive Electrodes

Indications For Use:

Adhesive electrodes are intended for use as the disposable, conductive adhesive interface between the patient's skin and the Electrical Stimulator. Top-Rank Adhesive Electrodes are intended to be used with marketed Electrical Stimulators, i.e. TENS (Transcuaneous Electrical Nerve Stimulation) and EMS (Electrical Muscular Stimulation). It is for OTC use.

Prescription Use _____ (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ___X___ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S